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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,033	04/21/2004	Rick J. Tresnak	P06654US00	7437

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DES MOINES, IA 50309-2721

EXAMINER

BUNIN, ANDREW M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/829,033		TRESNAK ET AL.	
	Examiner		Art Unit	
	Andrew M. Bunin		3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,14,16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-13,15,17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. (US 5197464) in view of Gallagher (US 3373735). Babb et al. disclose an adapter comprising a first tube 44 for attached to an endotracheal tube 26 and a second tube 48 capable of being attached to a bag-valve mask at 36. The adaptor includes a carbon dioxide indicator 62 in gaseous communication with the endotracheal tube 26, and isolated from the atmosphere. The carbon dioxide indicator 62 of Babb et al. still broadly reads as being mounted on an exterior portion 70 of the second tube 48. Exterior is defined as outer or external in relation to another feature (dictionary.com). Side 70 could still read as being an outer side of the second tube, therefore, the carbon dioxide indicator would be mounted on an exterior portion of a second tube. In addition, Gallagher teaches a medical-surgical tube including a paper indicator ring 22 surrounding perforations 28". The device of Gallagher also includes an outer wall 24" to isolate the indicator from the atmosphere. Gallagher teaches an indicator being mounted on an exterior portion of a tube. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Babb et al. to mount a carbon dioxide indicator on an exterior portion of a second tube

as well as include perforations around the tube in order to evenly indicate the levels of carbon dioxide around the entire tubular structure. Lastly, it is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claim over the prior art, barring a convincing showing of evidence to the contrary.

Babb et al. continues to disclose the adapter's first tube 44 having a tapered insertion end as shown in Figures 1 and 2. The adapter disclosed has first 44 and second 48 tubes axially aligned. In addition, the second tube 48 has an orifice 60 and the carbon dioxide indicator 62 covers the orifice and a further includes a casing 50 isolating the carbon dioxide indicator 62 from the atmosphere. As shown in Figures 2 and 3, the solution filled cavity 62 is cylindrical; therefore, the indicator covers some of the orifice 60. Babb et al. discloses the orifice 60 as being spaced around the second tube 48 and the carbon dioxide indicator 62 surrounds the second tube 48 over the orifice 60 as shown in Figure 3.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Gallagher and further in view of Williams (US 4691701). The carbon dioxide indicator 62 includes a ring of chemically treated colorimetric indicator paper 56. The dictionary defines a membrane as "a thin, pliable layer of tissue covering surfaces or separating or connecting regions...a piece of parchment." Based on this definition,

the membrane 56 that is chemically treated can be considered a colorimetric indicator paper 56. In addition, Gallagher teaches an indicator 22 as being an absorbent paper ring (column 2, lines 13-25). Although Gallagher doesn't explicitly teach the indicator 22 as being used for detecting carbon dioxide, Williams teaches an indicator that uses a similar litmus paper type material for detecting carbon dioxide. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Babb et al. to replace the indicator with the chemically treated indicator paper of Gallagher or Williams in order to detect carbon dioxide without the possibility of chemical leakage.

As for claims 9 and 10, Babb et al. also disclose the casing 50 as a clear ring. Casing 50 is a section of the housing 42 that is "molded or otherwise fabricated from a clear synthetic polymer such as polyethylene" (column 13, lines 59-61). In addition, the clear ring 50 has a C-shaped cross section defining a channel for receiving the carbon dioxide indicator 62. The cross section of a cylinder such as clear ring 50 has a C-shaped cross section as shown in Figure 2.

Claims 11-13, 15, are rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six (US 5058577). Babb et al. disclose an endotracheal tube 26, an adapter 34 having a first tube 44 attached to the endotracheal tube 26, and a second tube 48 capable of being attached to a bag-valve mask at 36 but does not disclose a stylet placed within the endotracheal tube and the adapter. In addition, Babb et al. doesn't disclose the stylet with a handle that interfaces with the second tube to

form a seal. However, Six teaches a "stylet is slidably received within an endotracheal intubation tube" (column 2, lines 18). Six also teaches a stylet 10 with a handle 34 that interfaces with a tube to form a seal as shown in Figures 1 and 2. Therefore, it would have been obvious at the time of the invention to a person having ordinary skill in the art to include the stylet taught by Six with Babb et al. adapter in order to facilitate insertion of the intubation tube into the airway of a patient. Babb et al. continue to teach a carbon dioxide indicator 62 on the adapter. Babb et al. and Six teach their respective devices as capable of being rapidly assembled as shown in the Figures. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to make the endotracheal tube, adaptor, carbon dioxide indicator and stylet pre-assembled and packaged as an assembly in order to be immediately ready for use. The prior art has shown that it has been well known in the art to package pre-assembled medical appliances as taught by Linder (US 4248236).

As for claim 15, Babb et al. disclose an orifice 60 in the perimeter of the second tube 48 with the carbon dioxide indicator 62 covering the orifice and a casing 50 isolating the carbon dioxide indicator 62 from the atmosphere.

Claims 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six (US 5058577). The method steps would have been obvious by the use of the device outlined in claims 11-13. Babb et al. discloses everything except for a bag-valve mask and a stylet within an endotracheal tube and adapter. However, Babb et al. discloses attachment of detector 34 to a

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ventilator hose 36 and states that "air present from mask ventilation prior to intubation" (column 4, lines 39-40). In addition, applicant has noted that bag-valve mask 48 attached to indicator 102 is considered prior art. Six teaches a "stylet is slidably received within an endotracheal intubation tube" (column 2, lines 18). Six also teaches a stylet 10 with a handle 34 that interfaces with a tube to form a seal as shown in Figures 1 and 2. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine a bag-valve mask in the prior art and include the stylet taught by Six with Babb et al. adapter to ventilate a patient and facilitate the insertion of an intubation tube into the airway of a patient.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six, and further in view of Kaigler et al. (US 5546934). Babb et al. and Six teach everything except the step engaging the bag-valve mask for one ventilation cycle. However, this is considered obvious in the art as well as Kaigler et al. discuss how a bag-valve mask "would then remain in its restored condition until the next bag squeezing operation and such cycle would be repeated as necessary" (column 1, lines 36-38). Therefore, Kaigler et al. teaches that it was well known in the art that there is a step engaging the bag-valve mask for one ventilation cycle.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-13, 15, 17, 19, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 8-13, and 17-20 of copending Application No. 10/981,036 in view of Babb et al. The claims in copending Application No. 10/981,036 read on all the claims of this application except claims 2 and 3. However, Babb et al. teaches that it is known for an adapter's first tube 44 to have a tapered insertion end as shown in Figures 1 and 2. In addition, the adapter disclosed has first 44 and second 48 tubes axially aligned. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the adapter or interconnection claimed in the copending application to have a tapered first tube for allowing it to fit into the end of an endotracheal tube as well as for the first and second tubes to be axially lined in order to line up the ventilating device through the second tube into the first tube as taught by Babb et al.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 1, 7, 8, 11, and 17 have been considered but are moot in view of the new ground(s) of rejection. As for claim 1, the carbon dioxide indicator 62 of Babb et al. still broadly reads as being "mounted on an exterior portion (70) of the second tube (48)." Exterior is defined as outer or external in relation to another feature (dictionary.com). Side 70 could still read as being an outer side of the second tube, therefore, the carbon dioxide indicator would be mounted on an exterior portion of a second tube. In addition, Gallagher teaches a medical-surgical tube including a paper indicator ring 22 surrounding perforations 28". The device of Gallagher also includes an outer wall 24" to isolate the indicator from the atmosphere. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Babb et al. to mount a carbon dioxide indicator on an exterior portion of a second tube as well as include perforations around the tube in order to evenly indicate the levels of carbon dioxide around the entire tubular structure. Lastly, it is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claim over the prior art, barring a convincing showing of evidence to the contrary.

As for claim 7, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "orifice in the tube") are not recited in the rejected claim(s).

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, Gallagher has taught an indicator surrounding a tube with many orifices as shown in Figures 3 and 5.

As for claim 8, Gallagher teaches an indicator 22 as being an absorbent paper ring (column 2, lines 13-25). Although Gallagher doesn't explicitly teach the indicator 22 as being used for detecting carbon dioxide, Williams teaches an indicator that uses a similar litmus paper type material for detecting carbon dioxide.

As for claims 11 and 17, Babb et al. and Six teach their respective devices as capable of being rapidly assembled as shown in the Figures. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to make the endotracheal tube, adaptor, carbon dioxide indicator and stylet pre-assembled and packaged as an assembly in order to be immediately ready for use. The prior art has shown that it has been well known in the art to package pre-assembled medical appliances as taught by Linder (US 4248236).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5421325, US 6427687, US 6123075, US 5468451, US 5749358, US 4827944, and US 4728499

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
10/7/05


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